



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

FINDING

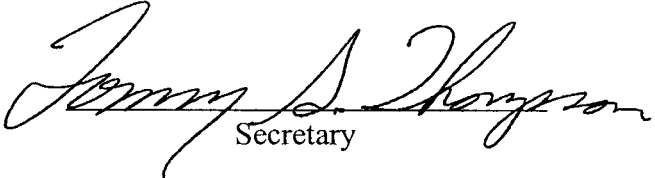
Advisory Committee on Heritable Disorders and
Genetic Diseases in Newborns and Children

I find that establishment of the Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children is specifically authorized by Title XXVI of the Children's Health Act of 2000 enacting Section 1111 of the Public Health Service Act.

I deem that such establishment is desirable to provide advice and consultation to the Secretary in connection with this Department's functions, that neither the Department nor any of its existing committees can feasibly perform these duties, and that a satisfactory plan for appropriate balance of committee membership has been submitted.

FEB 3 2003

Date


Secretary



THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201
CHARTER

ADVISORY COMMITTEE ON HERITABLE DISORDERS AND
GENETIC DISEASES IN NEWBORNS AND CHILDREN

Purpose

Title XXVI of the Children's Health Act of 2000, "Screening for Heritable Disorders," establishes a program to improve the ability of States to provide newborn and child screening for heritable disorders. Title XXVI enacts three sections of the Public Health Service (PHS) Act: sections 1109, 1110, and 1111.

Section 1109 of the PHS Act authorizes the Secretary to award grants to States, or a political subdivision of a State, or a consortium of two or more States, or political subdivisions of States to enhance, improve or expand the ability of States and local public health agencies to provide screening, counseling or health care services to newborns and children having or at risk for heritable disorders.

Section 1110 of the PHS Act authorizes the Secretary to award grants to eligible entities to provide for the conduct of demonstration programs to evaluate the effectiveness of screening, counseling or health care services in reducing the morbidity and mortality caused by heritable disorders in newborns and children.

The Secretary of Health and Human Services (HHS) is directed under section 1111 of the PHS Act to establish an Advisory Committee on Heritable Disorders in Newborns and Children (Committee). HHS has expanded the Committee to include genetic diseases and has renamed the Committee accordingly. The Committee's purpose is to provide to the Secretary advice and recommendations concerning the grants and projects authorized under section 1109 and technical information to develop policies and priorities for this program that will enhance the ability of the State and local health agencies to provide for newborn and child screening, counseling and health care services for newborns and children having or at risk for heritable disorders. Specifically, the Committee shall advise and guide the Secretary regarding the most appropriate application of universal newborn screening tests, technologies, policies, guidelines and programs for effectively reducing morbidity and mortality in newborns and children having or at risk for heritable disorders.

Authority

Section 1111 of the PHS Act, 42 U.S.C. 300b-10. The Committee is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), and 41 CFR Part 102-3, which sets forth standards for the formation and use of advisory committees.

Functions

The Advisory Committee on Heritable Disorders and Genetic Diseases in Newborns and Children shall review and report regularly on newborn and childhood screening practices, recommend improvements in the national newborn and childhood screening programs, and shall engage in the following activities:

- (1) Provide advice and recommendations to the Secretary concerning grants and projects awarded or funded under Section 1109 of the PHS Act;
- (2) Provide technical information to the Secretary for the development of policies and priorities for the administration of grants under Section 1109 of the PHS Act; and
- (3) Provide such recommendations, advice or information as may be necessary to enhance, expand or improve the ability of the Secretary to reduce the mortality or morbidity in newborns and children from heritable disorders.

Structure

The Committee structure shall not exceed 15 members, including the Chair and the ex-officio and liaison members. The total membership of the Committee shall be an odd number. The Secretary or his designee shall appoint as ex-officio members to the Committee, the Administrator of Health Resources and Services Administration (HRSA); the Directors of the Centers for Disease Control and Prevention (CDC), the National Institutes of Health (NIH), and the Agency for Healthcare Research and Quality (AHRQ); or their designees and representatives of such Federal agencies as the Secretary determines are necessary for the Committee to effectively carry out its functions. Other members and the Chair shall be selected by the Secretary or his designee from medical, technical, public health or scientific professionals with special expertise in the field of heritable disorders or in providing screening, counseling, testing or specialty services for newborns and children at risk for heritable disorders and from members of the public having special expertise about or concern with heritable disorders. The Committee shall also include, as liaison members, representatives of relevant medical professional and public health organizations. Of the appointed liaison members, at least one shall be a current voting member of the Secretary's Advisory Committee on Genetics, Health and Society, and another shall be a current voting member of the Secretary's Advisory Committee on Infant Mortality.

Members shall be invited to serve for overlapping terms of up to 4 years. However, any member appointed to fill a vacancy of an unexpired term shall be appointed for the remainder of such term. Members may serve after the expiration of their term until their successors have taken office. Terms of more than 2 years are contingent upon the renewal of the Committee by appropriate action prior to its expiration.

Coordination, management, and operational services shall be provided by the Office of the Associate Administrator, Maternal and Child Health Bureau, HRSA, with direction and guidance from the Assistant Secretary for Health. HRSA will select the Designated Federal Official to attend each Committee meeting and ensure that all advisory committee procedures are within applicable statutory, regulatory, and HHS General Administration Manual directives. Agenda development will be coordinated by HRSA with the ex-officio members from CDC, NIH, and AHRQ and the Chair of the Committee. The Committee shall report to the Secretary through the Office of the Assistant Secretary for Health.

A quorum for the conduct of business by the full Committee shall be a simple majority of the appointed voting members. Liaison members are nonvoting members.

As necessary, standing and ad hoc subcommittees composed of members of the parent committee may be established to perform specific functions within the Committee's jurisdiction. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

The Committee shall be able to call upon special consultants, assemble ad hoc working groups, and convene hearings as necessary to assist in the work of the Committee.

Meetings

Meetings shall be held at least twice a year or more often as deemed necessary by the Chair in consultation with the Designated Federal Official. The Designated Federal Official or his/her designee shall be present at all meetings of the full committee and may elect to participate on an ad hoc basis in workgroup and subcommittee meetings or hearings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated. Notice of all meetings shall be given to the public.

Meetings shall be conducted and records of the proceedings kept, as required by applicable law, regulation and the HHS General Administration Manual.

Compensation

Members who are not Federal employees shall be paid at a rate of \$250 per day for each day they are engaged in the performance of their duties as members of the Committee. Members shall receive per diem and travel expenses as authorized by Section 5 U.S.C. 5703 for persons employed intermittently in Government service. Members who are officers or employees of the United States Government shall not receive compensation for service on the Committee.

Annual Cost Estimate

Estimated annual cost for operating the Committee, including compensation and travel expenses for members but excluding staff support, is \$217,420. Estimated annual person-years of staff support required are 1.5 at an estimated annual cost of \$165,741.

Reports

In the event a portion of a meeting is closed to the public, an annual report shall be prepared which shall contain, at a minimum, a list of the members and their business addresses, the Committee's function, dates and places of meetings, and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, this Charter will terminate 2 years from the date of the Secretary's signature.

APPROVED:

FEB 3 2003

Date

Secretary

